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22
23 IN THE UNITED STATES DISTRICT COURT
24
25 FOR THE DISTRICT OF ARIZONA

26 IN RE: Bard IVC Filters Products
27 Liability Litigation,

28 No. 2:15-MD-02641-DGC

THE PARTIES' JOINT STATUS
REPORT FOR THE DECEMBER 9,
2016 CASE MANAGEMENT
CONFERENCE

1 In accordance with Paragraph E of Case Management Order No. 18 [Doc. 3685],
 2 the Parties hereby submit their Joint Status Report for the December 9, 2016 Case
 3 Management Conference.

4 **I. Fact Discovery**

5 The following depositions have been completed:

| | | |
|----|-------------------|-----------------------------------|
| 6 | December 15, 2015 | 30(b)(6) re FDA Warning Letter |
| 7 | January 11, 2016 | Kay Fuller |
| 8 | January 20, 2016 | Continued 30(b)(6) re FDA Warning |
| 9 | | Letter |
| 10 | March 18, 2016 | 30(b)(6) re corporate structure |
| 11 | April 27, 2016 | 30(b)(6) re ESI systems structure |
| 12 | May 3, 2016 | Dr. Murray Asch |
| 13 | May 11, 2016 | Carol Vierling |
| 14 | May 17, 2016 | Anne Bynon |
| 15 | May 24, 2016 | Len DeCant |
| 16 | June 2, 2016 | John DeFord |
| 17 | June 9, 2016 | Bret Baird |
| 18 | June 16, 2016 | Robert DeLeon |
| 19 | June 17, 2016 | Joe DeJohn |
| 20 | July 18, 2016 | Abithal Raji-Kubba |
| 21 | July 27, 2016 | Bill Little |
| 22 | July 27, 2016 | Judy Ludwig |
| 23 | July 29, 2016 | John Wheeler |
| 24 | August 9, 2016 | Maureen Uebelacker |
| 25 | August 16, 2016 | Daniel Orms ¹ |
| 26 | August 19, 2016 | Mary Edwards |

27 ¹ Mr. Orms was deposed in the state court action Austin v. C.R. Bard, et al., in Broward
 28 County, Florida, and cross-noticed in the MDL for coordination purposes.

| | | |
|----|--------------------|-----------------------------|
| 1 | August 24, 2016 | Cindi Walcott |
| 2 | August 30, 2016 | 30(b)(6) re REACH program |
| 3 | September 7, 2016 | Steve Williamson |
| 4 | September 7, 2016 | 30(b)(6) re Sales/Marketing |
| 5 | September 7, 2016 | Kevin Shifrin |
| 6 | September 16, 2016 | Jack Sullivan |
| 7 | September 19, 2016 | Brian Doherty |
| 8 | September 23, 2016 | Holly Glass |
| 9 | September 29, 2016 | John Van Vleet |
| 10 | October 11, 2016 | Chris Ganser |
| 11 | October 18, 2016 | Natalie Wong |
| 12 | November 11, 2016 | Robert Cortelezzi |

13 The following depositions have been scheduled:

| | | |
|----|------------------|-------------------------------------|
| 14 | December 6, 2016 | David Peeler, M.D. |
| 15 | January 4, 2017 | John Kaufman, M.D. |
| 16 | January 6, 2017 | 30(b)(6) re Key Opinion Leaders |
| 17 | January 18, 2017 | 30(b)(6) re Meridian/Denali |
| 18 | January 18, 2017 | Kim Romney |
| 19 | January 26, 2017 | 30(b)(6) re Failure Rate Thresholds |
| 20 | February 2, 2017 | Mike Randall |

21
 22 The defendants have offered dates for the depositions of Mark Wilson and Scott
 23 Randall, but Plaintiffs have not yet confirmed available counsel for those dates.

24 The defendants have either scheduled the depositions or offered dates for all of the
 25 past or present employees and consultants whom the plaintiffs have identified and whom
 26 have not retained their own attorneys. However, several of the third-party physicians the
 27 plaintiffs seek to depose have retained their own counsel (or are represented by counsel

1 for the university that employs them). The parties are working with those attorneys to
2 coordinate their depositions before the close of discovery:

- 3 • Scott Trerotola, M.D., a Bard consultant
4 • Anthony Venbrux, M.D., a Bard consultant
5 • S. William Stavropoulos, M.D., a Bard consultant
6 • Frank Lynch, M.D., a Bard consultant
7 • Gary Cohen, M.D., a Bard consultant

8 **II. ESI Discovery Status**

9 A. Plaintiffs' Report on ESI Production and Plaintiffs' Review of Same

10 Bard began its expedited ESI production on September 15, 2016. Bard made
11 multiple rolling productions over the next 5 weeks, ending October 22, that totaled more
12 than 4.5 million pages and nearly 1 million documents. While these productions were
13 ongoing, Plaintiffs commenced a project with their ESI vendor to utilize predictive coding
14 in order to expedite and to make more efficient their review of Bard's produced ESI –
15 particularly in light of the tight discovery deadlines in this case. Beginning the week of
16 October 23, Plaintiffs immediately engaged a small dedicated a team of knowledgeable
17 lawyers, including both Co-Lead Counsel, to train the predictive coding program

18 That process included a two-day in-person assessment phase, during which that
19 team determined the rules for coding, followed by “training” of the software through the
20 iterative review of training sets. Unfortunately, although the program was supposed to
21 permit concurrent coding of training sets by different users (allowing each of the training
22 attorneys to code distinct sets concurrently), that feature failed to work, and neither
23 Plaintiffs’ vendor nor the programmer was able to fix the problem prior to completion of
24 training. As a result, only one person could train at a time rather than multiple team
25 members concurrently. Those attorneys then took turns coding the training sets, resulting
26 in significant delay in the completion of the training. Rather than a week, training took
27 nearly three. Nonetheless, Plaintiffs were able to utilize predictive coding to identify a
28 significantly smaller subset of documents for second stage review.

1 Thereafter, Plaintiffs have commenced a PSC-wide document review of
2 approximately 150,000 documents – including those documents identified by the
3 predictive coding and those that could not be evaluated by predictive coding (including a
4 variety of overlong documents, images, or otherwise illegible documents within Bard's
5 productions). Plaintiffs presently have 21 firms dedicating in excess of 40 lawyers and
6 legal professionals who are engaged in that review process – many of whom are
7 dedicating 25 or more hours per week to the process.

8 Nonetheless, due to the quantity of documents that need to be reviewed and the
9 delays in the predictive coding process, Plaintiffs do not anticipate that they will complete
10 their review before the end of the year. Plaintiffs will be prepared to address the status of
11 that review and update the Court on progress at the case management conference.

12 Additionally, Plaintiffs have identified to Bard several custodians (whose
13 productions were either agreed upon by the parties or ordered by the Court) whose ESI
14 appears not to have been produced. For three such custodians, Bard has not produced any
15 documents; for another five, Bard has produced less than 200 documents, and for a sixth,
16 less than 300. Plaintiffs have requested that Bard collect and produce their ESI. Bard is
17 investigating the circumstances of the identified custodians.

18 **B. Bard's Report**

19 Bard has now completed its document production. At plaintiffs' request, the parties
20 are working on completing a sampling exercise whereby they are testing the pool of
21 documents and files that were not identified for collection by their agreed search process
22 (the "non-responsive pool"). If the parties learn through that testing that their search
23 methodology did not perform consistently with their expectations for the identification of
24 relevant documents, they will meet and confer regarding additional search or searches
25 through the non-responsive pool to identify relevant documents.

26 With regard to the custodians referenced by the plaintiffs, Bard has been
27 investigating the issues raised and communicating with its ESI vendor. That investigation
28 is nearing completion. Bard will provide the plaintiffs a summary of what is learned in

1 advance of the December 9th conference. At this preliminary juncture, however, with a
2 couple of possible exceptions, it appears that all available ESI has been produced.

3 **III. Bellwether Process**

4 Pursuant to CMO No. 11, Paragraph IV A.1, the parties must exchange their lists of
5 10 plaintiffs selected from PFS/DFS Group 1, from which each side may designate 4 of
6 their 10 plaintiff selections for automatic inclusion in Discovery Group 1.

7 The parties have agreed to meet and confer regarding the selection of the final four
8 cases for Discovery Group 1. If the parties are unable to jointly identify the final four
9 cases to be included in Discovery Group 1, they must make separate submissions to
10 facilitate the Court's selection of the final four cases for inclusion in Discovery Group 1.
11 The parties must complete that exchange by Friday, December 9, 2016.

12 **IV. Remand of Mature Cases**

13 A. Plaintiffs' position

14 Co-Lead Counsel have conferred with counsel of record for each of the Mature
15 Cases, and those attorneys have confirmed that each of those cases is ready for remand.
16 The Mature Cases all involve early devices for which discovery is essentially complete
17 and were referred to this MDL for discovery relating the FDA Warning Letter, which
18 Plaintiffs have essentially completed. For reasons previously discussed, those cases were
19 all nearly ready for trial at the time of their transfer to this Court. It has always been
20 anticipated that these cases would be remanded early, and plaintiffs in all these cases are
21 prepared for remand to proceed to trial.

22 To the extent that Bard contends below the cases should remain in the MDL
23 pending further unidentified discovery and expert disclosures, retaining the cases here will
24 not affect Bard's ability to take such discovery in the MDL or even potentially to use it in
25 those cases. In CMO 18, this Court set deadlines that complete expert discovery by July
26 14, 2017. Depending upon individual trial settings, it is likely that all of that discovery
27 will be complete in the MDL before the any of the remand cases are tried. And, as has
28 been the case with the *Austin* Florida state-court case (and several other state-court cases

1 in Arizona), the discovery in the MDL can be coordinated and cross-noticed in those cases
2 so that they are not further delayed.

3 Moreover, the arguments that Bard raises below are appropriate for individual
4 consideration by the judges on remand. The judges who will try the cases are in the best
5 position to determine when the cases will go to trial and what evidence can and should be
6 permitted at them.

7 B. Defendants' position

8 Respectfully, Bard submits that any remand of the Mature Cases is premature.
9 While the Plaintiffs may have "essentially completed" their fact discovery (as they claim),
10 Bard has not. The plaintiffs are presently attempting to block or delay depositions Bard
11 considers critical to that issue (as explained in the Section that follows). In addition, the
12 parties have not yet conducted any expert discovery regarding the FDA warning letter.
13 Nor have the parties had the opportunity yet to conduct expert discovery regarding the
14 allegations made by Kay Fuller.

15 If the plaintiffs are now willing to enter a binding stipulation that they will not
16 offer any evidence whatsoever in the mature cases regarding the FDA warning letter or
17 Kay Fuller's claims, then the plaintiffs' request might have some merit. Bard tends to
18 agree, that at least from the standpoint of factual and expert development, the mature
19 cases might be ripe for remand in that scenario. Absent such a stipulation, however, they
20 are not. Readiness for remand should not be contingent on the completion of discovery by
21 only one side, i.e., the plaintiffs. Nor should Bard be deprived of the opportunity to
22 develop and offer expert testimony to explain the regulatory issues surrounding the factual
23 evidence developed regarding both the warning letter and the claims about the FDA
24 clearance process made by Kay Fuller. The plaintiffs persuaded the Judicial Panel on
25 Multidistrict Litigation to create this MDL in the first instance by arguing that a
26 coordinated proceeding was the only efficient means to explore these "new" issues.
27 Likewise, a coordinated proceeding will be the only efficient vehicle for Bard to develop
28 its defenses to those allegations. Hence, absent a stipulation by the plaintiffs negating the

1 relevance of those issues, remand of the mature cases should not occur until the
 2 completion of expert discovery in this MDL.

3 One other consideration counsels against the remand of those cases at this juncture.
 4 A remand of the cases now will disrupt the bellwether process in this MDL. The parties
 5 have previously agreed that additional discovery regarding "loose ends" remains to be
 6 completed in each of those cases. See Stipulation Regarding Status of Mature Cases
 7 [Doc. 914]. The completion of those activities, as well as other pre-trial proceedings in
 8 the transferor courts would inevitably delay any trials until mid- or late 2017. Any trial
 9 settings for those cases would inevitably interfere with (and possibly even disrupt) final
 10 preparations for a bellwether trial in this Court. Additionally, such a scenario would
 11 dilute the significance of any trial in this Court, and the potential for bellwether trials to
 12 guide a possible resolution of the litigation.

13 For those reasons, Bard asks that the mature cases not be remanded at this time.

14 **V. Dispute Regarding Depositions of Plaintiffs' Counsel**

15 A. Plaintiffs' position

16 On November 28 (one week prior to this filing), Bard made the extraordinary
 17 request to depose two of the lawyers who have been part of the PLC in this MDL – John
 18 Dalimonte and Troy Brenes – regarding their contacts with the Food and Drug
 19 Administration (“FDA”). Messrs. Dalimonte and Brenes previously responded to Bard’s
 20 discovery requests regarding FDA contacts and provided information that they had had
 21 such contacts. Both identified their contacts with the FDA in interrogatory responses and
 22 provided the documents relating to those contacts. While the parties have not yet had an
 23 actual meet and confer regarding their dispute, it is clear that the parties disagree as to
 24 whether Bard has any right to take these depositions.² Accordingly, in response to Bard’s
 25 request, Plaintiffs suggested that the parties agree to an expedited briefing schedule.

27 ² Suffice it to say that Plaintiffs disagree with Bard’s unsubstantiated claims and leaps of
 28 logic regarding the FDA’s actions as being directly caused by these attorneys. Despite the
 rhetoric of Bard’s position below, there is a wide gap between the contacts with the FDA

Bard, however, now seeks to proceed with the dispute as an issue for the December 9 case management conference. As this Court can appreciate, a party's request to depose the opposing attorneys in a case raises significant and substantial issues well beyond those in normal discovery. Plaintiffs first learned of Bard's arguments and positions on this dispute on the evening of December 3 when Bard's counsel conveyed its draft of the arguments that are set forth in subsection B below. Plaintiffs do not believe it appropriate to have to respond to Bard's arguments on this issue in less than 24 hours. Indeed, neither Mr. Dalimonte nor Mr. Brenes has yet had an opportunity to be heard. Plaintiffs request a reasonable time to brief the issue given its significance and will do so on an expedited basis.

11 B. Defendants' position

12 Bard has requested the opportunity to depose Messrs. John Dalimonte and Troy
 13 Brenes, the two plaintiffs' attorneys who have admitted contacting the FDA about Bard's
 14 filters. Neither Bard nor its attorneys have made this request lightly, as they recognize
 15 that depposing counsel can be "disruptive" of the adversarial process. See Shelton v. Am.
 16 Motors Corp., 805 F.2d 1323, 1327 (8th Cir. 1986). Here, however, the attorneys have
 17 turned themselves into significant fact witnesses, and are critical witnesses to Bard's
 18 defense.

19 If – as the plaintiffs contend – this issue is not ripe for presentation to the Court, it
 20 is because the plaintiffs have failed to respond to Bard's repeated efforts to move the issue
 21 along. In their discovery response, Messrs. Dalimonte and Brenes admitted having
 22 communicated with the FDA, but they failed to provide most of the details of those
 23 conversations sought by the discovery requests. Bard's counsel then sent letters to both
 24 attorneys, copied to plaintiffs' co-lead counsel, seeking to address the deficiencies in the
 25 responses. Mr. Brenes never acknowledged the letter or responded to it. Mr. Dalimonte

26
 27 _____
 28 and the FDA's independent actions in issuing the Warning Letter. Simply, the conduct of
 these attorneys not is at issue in this MDL.

1 eventually sent a response, but again failed to provide much of the detail requested. Only
 2 then did Bard request depositions of the two attorneys.³

3 Bard submits this issue needs to be addressed soon, so that the depositions can
 4 proceed (if the Court permits) and any follow-up discovery completed prior to the close of
 5 fact discovery. If the plaintiffs believe additional efforts to meet and confer might resolve
 6 or narrow the issues, Bard believes the plaintiffs should engage in that conversation this
 7 week, prior to the December 9th conference.

8 If the Court believes formal briefing would be helpful, Bard is of course happy to
 9 file a brief explaining its position. The issue, however, is straightforward. Specifically,
 10 the attorneys' admissions in their discovery responses suggest a direct link between their
 11 activities and the FDA investigation of Bard that led to the issuance of the 2015 warning
 12 letter. A party (or the party's counsel) cannot seek agency action to gain an advantage in
 13 litigation, and then resist discovery of its efforts. Thus, courts allow "liberal discovery of
 14 statements made or documents submitted to a governmental agency prior to the initiation
 15 of an investigation" Three Crown Ltd. P'ship v. Salomon Bros., No. 92 Civ. 3142
 16 (RPP), 1993 WL 277182, at *2 (S.D.N.Y. July 21, 1993). Courts have observed that "[a]
 17 well-travelled route to achieving relief in civil litigation has been to persuade the
 18 government to take action against a party and thereby gain, if possible, the advantage of
 19 collateral estoppel in later civil litigation against that party. The party who travels that
 20 route should not be protected from disclosure of its statements." Id.; Cante v. Baker, No.
 21 07-CV-1716 (ERK), 2008 WL 2047885, at *1 (E.D.N.Y. May 9, 2008); Reed v. Advocate
 22 Health Care, No. 06 C 3337, 2007 WL 2225901, at *2 (N.D. Ill. Aug. 1, 2007); Bank of
 23 Am., N.A. v. Terra Nova Ins. Co., 212 F.R.D. 166, 175 (S.D.N.Y. 2002); Info. Res., Inc.

24
 25 ³ In this submission, the plaintiffs have for the first time suggested Bard is somehow
 26 required to serve a subpoena for those depositions, and that the dispute is somehow not
 27 ripe until Bard does. That position is antithetical to how this MDL has functioned from
 28 the outset. Bard has not once requested, much less insisted on, a subpoena for any witness
 over which it had any control. In turn, the parties have presented to the Court several past
 disputes over deponents, despite the lack of subpoenas.

1 v. Dun & Bradstreet Corp., 999 F. Supp. 591, 593 (S.D.N.Y. 1998). Hence, as this Court
2 previously recognized, communications with the FDA about Bard's IVC filters should be
3 discoverable.

4 The evidence revealed thus far demonstrates that Mr. Dalimonte made a number of
5 phone calls to the FDA's Massachusetts and New Jersey regional offices to discuss Bard's
6 filters. See Attorney John A. Dalimonte Answers to Defendant's Interrogatories (attached
7 as Exhibit "A"). Thereafter, and in response to those calls, a representative of the FDA's
8 New Jersey regional office contacted Mr. Dalimonte in May of 2014. A telephone call
9 was scheduled, and on May 15, 2014, a conference call among Mr. Dalimonte, Mr.
10 Brenes, and two FDA officials took place. Id. at 3; see also Attorney Troy A Brenes'
11 Answers to Defendant's Interrogatories (attached as Exhibit "B"). (Emails indicate that
12 Mr. Ramon Lopez was aware of the call, but did not participate. See Email dated May 14,
13 2014 attached as Exhibit "C"). Following the call, Mr. Dalimonte and perhaps Mr. Brenes
14 forwarded a number of documents related to their ongoing litigation against Bard, and
15 they continued over the next year to furnish additional documents to the agency.

16 The link between Mr. Dalimonte's calls and the subsequent FDA investigation of
17 Bard's filters is further demonstrated by an FDA internal document produced pursuant to
18 the Freedom of Information Act. That document (attached as Exhibit "D") indicates that
19 the New England regional office ("NWE-DO") received a call from a "complainant"
20 regarding Bard's filters. The timing of that call (March 7, 2013) is consistent with Mr.
21 Dalimonte's admission that he first reached out to the New England office "a year or so"
22 prior to his May 2014 conversation with the FDA. See Email dated May 14, 2014
23 attached as Exhibit "E". According to the FDA, the caller (presumably Mr. Dalimonte)
24 reported that Bard had allegedly not reported "1000 adverse events" to the FDA. The
25 FDA document indicates that the agency referred the report to the New Jersey regional
26 office and to the Los Angeles regional office. It is likely not a coincidence that the FDA's
27 Los Angeles office subsequently came to Tempe with the sole goal of inspecting Bard
28 Peripheral Vascular's complaint files regarding IVC filters. It is also likely not a

1 coincidence that the FDA issued its warning letter only a month after Mr. Dalimonte
 2 wrote a particularly inflammatory e-mail to his contacts at the FDA. See E-mail dated
 3 June 3, 2015 attached as Exhibit "F."

4 While Bard has been able to reconstruct part of this chronology, there are a myriad
 5 of additional details that only depositions of Messrs. Brenes and Dalimonte can provide.
 6 As one example, Bard cannot ascertain from the information provided what Messrs.
 7 Dalimonte and Brenes reported to the agency; what "remedy," if any, they requested from
 8 the agency; and what the FDA officials said in response. Bard should be entitled to
 9 explore the specifics of these various phone calls, including a detailed description of all
 10 statements made to the FDA. Likewise, Bard should be entitled to learn how the FDA
 11 employees responded and what they said. Bard has exhausted other options for obtaining
 12 that information (such as additional FOIA requests to the FDA), and the regulations
 13 generally prohibit private litigants from deposing FDA officials. Hence, having taken the
 14 "well-traveled route" of attempting to persuade the government to take action, these
 15 attorneys should be required to disclose the details of their efforts. See Three Crown Ltd.
 16 P'ship, 1993 WL 277182, at *2.

17 The Ninth Circuit has not established a standard for assessing requests to depose
 18 opposing counsel. Other courts have taken varying approaches. Compare Shelton, 805
 19 F.2d at 1327 (articulating three-prong standard), with In re Subpoena Issued to Dennis
 20 Friedman, 350 F.3d 65, 72 (2d Cr. 2003) (adopting "flexible" approach); see also Younger
 21 Mfg. Co. v. Kaenon, Inc., 247 F.R.D. 586, 588 (C.D. Cal. 2007) (discussing absence of
 22 controlling authority in the Ninth Circuit). Regardless what test applies, the majority of
 23 courts permit depositions of opposing attorneys whose own conduct has become at issue.
 24 See, e.g., Johnston Dev. Group, Inc. v. Carpenters Local Union No. 1578, 130 F.R.D. 348,
 25 352 (D.N.J. 1990) ("In cases where the attorney's conduct itself is the basis of a claim or
 26 defense, there is little doubt that the attorney may be examined as any other witness.");
 27 accord Am. Cas. Co. of Reading, PA v. Krieger, 160 F.R.D. 582, 586 (S.D. Cal. 1995).

28

1 In this instance, the conduct of Mr. Dalimonte and Mr. Brenes is directly relevant
2 to Bard's defense to the plaintiffs' allegations pertaining to the FDA warning letter. By
3 attempting to instigate an FDA investigation (apparently successfully), the attorneys have
4 transformed themselves into fact witnesses. Bard should therefore be able to depose the
5 two attorneys, with the understanding that the questioning will be limited to their
6 communications with the FDA.

7 **VI. Dispute Regarding Class Action 30(b)(6) Deposition Notice**

8 The parties in the *Barraza* medical monitoring class action have a dispute about
9 whether Bard is obligated to produce a witness to testify to eight topics in Class Plaintiffs'
10 Rule 30(b)(6) deposition notice (attached as Exhibit G to this joint status report).
11 Plaintiffs served this notice in late September, and the parties have met and conferred
12 extensively on the scope of the notice, with Plaintiffs withdrawing multiple of the topics.

13 A. Plaintiffs' position

14 Although Plaintiffs have fully withdrawn or narrowed a number of topics after
15 numerous meet-and-confers, Bard has yet to agree to produce a single witness on a single
16 topic in the notice. Its counsel has stated that prior testimony, documents, or written
17 discovery are sufficient to cover the topics, that the topics are too broad to allow for the
18 preparation of a corporate witness or are disproportional to the needs of the case, or are
19 irrelevant to class certification issues.

20 Plaintiffs' position is that prior testimony from individual witnesses, to the extent
21 that Bard has identified it, is inadequate as to the remaining topics, given the burden,
22 additional to and distinct from the personal injury plaintiffs in the MDL, that Plaintiffs
23 must carry at class certification – to show the predominance of issues common to all Class
24 members. Much of that evidence must come from corporate testimony, and not from
25 inevitably fragmentary evidence from individual witnesses who have no obligation to
26 prepare to testify as to certain topics, and which Bard could potentially disclaim as not the
27 position of the company. *See Sprint Commc'n Co., L.P. v. Theglobe.com, Inc.*, 236
28 F.R.D. 524, 528 (D. Kan. 2006) (holding that Rule 30(b)(6)'s "requirements negate any

1 possibility that an inquiring party will be directed back and forth from one corporate
2 representative to another, vainly searching for a deponent who is able to provide a
3 response which would be binding upon that corporation.”).

4 Bard’s overbreadth and proportionality objections are also unavailing, as they
5 misconstrue the topics at issue. The topics are intended to capture Bard’s decision-
6 making about core communications that applied to and affected all Class members, and
7 not individual communications that Bard has stated it would have to gather and review to
8 offer a witness on these communications. Such decision-making is a routine topic for
9 Rule 30(b)(6) depositions and not disproportional to the needs of the case here.

10 B. Defendants’ position

11 Plaintiffs originally requested the deposition(s) of a Bard Corporate
12 Representative(s) on 19 topics identified in the attached Notice. Through the meet and
13 confer process, a number of topics have been withdrawn as having been previously
14 addressed through other prior discovery, including prior 30(b)(6) depositions taken by
15 members of the Plaintiffs' Steering Committee, or are the subject of recently-served
16 written discovery. For example, Plaintiffs originally sought a witness to speak to "Bard's
17 tracking of adverse event information" and the organizational structure of various
18 departments. Through the meet and confer process, Defendants' counsel has spent a great
19 deal of time identifying documents produced and listed on subject-matter indices years
20 ago (such as organizational charts and sales data) and prior 30(b)(6) depositions covering
21 subject matters listed in Plaintiffs' notice. Defendants' counsel has likewise spent a great
22 deal of time attempting to discern the precise subject matter that Plaintiffs intended to
23 cover with their notice, repeatedly seeking clarification and, in many instances, explaining
24 to Plaintiffs why it is not possible to present a witness on the topics sought, whether
25 because Bard does not have the information requested beyond that which exists in ESI
26 previously produced or the minds and memories of individuals involved in these issues
27 from 2003 to the present, or various other reasons, as discussed more fully below.

28

Only upon seeing Plaintiffs' portion of this joint submission, provided to Defendants' counsel mid-day on the due date, do Defendants have the benefit of certain clarifications they have sought throughout the meet and confer process. Plaintiffs also appear to abandon their prior positions with respect to certain topics, certain of which are documented in their own meet and confer correspondence. The topics that remain in dispute are topics 5, 7, 8, 9, 10, 13, 14, and 15. The Parties' respective positions regarding these topics are set forth below:

C. Specific Topics in Dispute

1. Topic 5 – Communications to physicians, healthcare professionals, or healthcare providers, relating to the safety or efficacy of Bard IVC Filters, including Bard's consideration of such communications, whether or not sent. Such communications include, but are not limited to, Dear Doctor letters and other notices.

| Plaintiffs' Position | Defendants' Position |
|---|---|
| <p>This topic seeks testimony concerning Bard's communications to physicians, healthcare professionals, and healthcare providers concerning the safety and efficacy of Bard IVC Filters, and Bard's internal deliberations concerning these communications. This topic focuses on a limited number of Bard's communications that were the result of corporate planning and direction, including Dear Doctor letters and communications from Bard personnel that interact directly with doctors – Bard's centrally trained sales force. These communications are standard; they are part of an effort that Bard speaks with a coherent and consistent voice concerning IVC Filters. To defeat class certification, Bard has argued, and presumably will argue again, that the question of whether a medical monitoring program is appropriate or not is not susceptible to class adjudication because it raises issues that are specific to individual class members, including device-specific issues. Plaintiffs are entitled to inquire about whether Bard, in planning and communicating its communications to the healthcare community, differentiated among class members in a way that raises the individual questions that they will argue defeats class certification.</p> <p>Bard's assertion that this topic requires inquiry into the thought processes of</p> | <p>Through the meet and confer process, Defendants explained their view that it would be impossible for a witness or witnesses to comply with this topic, as drafted and as previously clarified by Plaintiffs, as it would seek a witness to speak to the mental impressions and thought processes of hundreds of employees spanning a 13-year time period.</p> <p>Plaintiffs previously attempted to clarify the intended scope of the topic, but their "clarification" expanded the scope to include (1) "official" communications made by Bard to physicians, (2) any training materials used with IVC filter sales representatives, (3) <u>any documents prepared by sales representatives for use in discussing filters with doctors</u>, and (4) the <u>decision-making process</u> surrounding the issuance of Dear Doctor Letters and "other" mass corporate or official communications made by Bard that were made or that were contemplated regarding IVC filters.</p> <p>Only now, in their draft of this joint submission, do Plaintiffs appear to limit this topic to "communications that were the subject of corporate planning and direction, including the Dear Doctor letters and communications from Bard personnel that interact directly with doctors."</p> |

1 hundreds of individuals over a 13-year
 2 period is not correct. The topic involves
 3 corporate decision-making, which is not an
 4 unusual area of inquiry for a Rule 30(b)(6)
 5 notice. It requires Bard to identify those
 6 decision-makers and to testify to the
 7 process of putting together these core
 8 communications, which are common to all
 9 class members and relevant to class
 10 certification.

1 Any Dear Doctor letters or similar "mass"
 2 communications made by Bard to
 3 physicians have been produced and are
 4 known to Plaintiffs. Additionally,
 5 although Plaintiffs state in their
 6 preliminary statement that they do not
 7 intend for any of their topics to seek
 8 individual correspondence from sales
 9 personnel to doctors, if not that, then
 10 Defendants do not know what information
 11 Plaintiffs intend to capture by
 12 "communications from Bard personnel
 13 that interact directly with doctors", as
 14 Plaintiffs appear to indicate the
 15 communications sought are separate and in
 16 addition to "mass" communications like
 17 the aforementioned Dear Doctor letters.
 18 As a result, as with Plaintiffs' prior
 19 attempts to clarify and seek information
 20 including "any documents prepared by
 21 sales representatives for use in discussing
 22 filters with doctors," Defendants do not
 23 fully understand what Plaintiffs seek, as
 24 Defendants remain unable to discern the
 25 outer scope of what communications
 26 Plaintiffs intend to capture. Moreover,
 27 although Plaintiffs indicate they seek
 28 discovery regarding "the process of putting
 together core communications", when
 counsel for Defendants specifically asked
 whether Plaintiffs seek a witness regarding
 policies and procedures, Plaintiffs declined
 to provide that clarification.

1 As a result, Defendants do not believe that
 2 it is feasible for a witness or witnesses to
 3 undertake to make themselves
 4 knowledgeable about certain sub-topics of
 5 this topic, including what mass
 6 communications were contemplated but
were not sent, as so doing would
 7 necessarily require the interview of dozens
 8 or hundreds of individuals employed by
 9 Defendants at various points spanning a
 10 13-year time period. Nor do Defendants
 11 believe that it is feasible for a witness or
 12 witnesses to become knowledgeable
 13 regarding all documents prepared by sales
 14 representatives for use in discussing IVC
 15 filters with doctors, particularly given that,
 16 as Defendants have explained to Plaintiffs,
 17 such documents will generally exist only
 18 in ESI. Defendants note that the Court has
 19 previously ruled that sales representative
 20 discovery, outside of that involving

| | |
|-----------------------------|---|
| | <p>national and regional level managers, should be undertaken after remand or as part of the bellwether process.</p> <p>Plaintiffs have previously declined to articulate why the subject matter of this topic (and its many sub-topics) is necessary at the class-certification discovery stage of this case. Although Plaintiffs now for the first time articulate the rationale that inquiry into whether Bard's communications to physicians or healthcare community differentiated among class members, the information necessary to answer that question is readily apparent on the face of the very communications of which Plaintiffs now purport to limit this topic, and Plaintiffs have logs indicating to which physicians/healthcare providers the Dear Doctor Letter and Dear Colleague Letter were sent.</p> <p>As Plaintiffs are well-aware, Rule 26 governs the scope of permissible discovery with respect to a case brought under Rule 23, and Defendants believe certain of the proportionality factors counsel heavily in favor of denying this discovery. Specifically, regarding any information sought that exists outside the mental thoughts of individuals, Plaintiffs have all documents on these issues, so the Parties' relative access to relevant information is not largely disparate. Moreover, regarding the importance of the discovery in resolving the issues and whether the burden of the discovery outweighs any benefit, Plaintiffs' articulated reason does not support the discovery, as it does not seek information which Plaintiffs do not already have.</p> <p>Because Defendants now have the benefit of Plaintiffs' clarification of this topic, Defendants will attempt to reconvene the meet and confer process regarding this topic and report to the Court regarding those efforts at the upcoming Case Management Conference.</p> <p>2. Topic 7 – Bard's communications to physicians, healthcare professionals, or healthcare providers regarding the replacement of filters in the market and/or the introduction of new filters into the market, and Bard's consideration of whether to send such communications, whether or not sent.</p> |
| <u>Plaintiffs' Position</u> | <u>Defendants' Position</u> |

| | |
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| | <p>This topic - concerning Bard's communications to physicians, healthcare professionals, or healthcare providers regarding the transitions from one generation of filter to the next - is focused on the same set of core communications at issue in Topic 5. Bard's objections mirror those it asserts as to Topic 5 – that it requires testimony over the entire class period and would require interviews with a large number of individuals.</p> <p>As to the first objection, testimony about corporate decision-making as to core documents and communications does not require interviews with all of the individuals tasked with conveying a common communication, but only with those who shaped the communications.</p> <p>Second, the objection that this case covers thirteen years cuts against Bard. A single deposition in a multi-state class action, brought by eleven plaintiffs and seeking a multi-state remedy, is not disproportional, given this case's scope. Further, even if Bard asserted that it could not produce a single witness to cover the entire class period, that does not relieve it of its obligations to take reasonable steps to educate such a witness, or to identify the time period for which it can provide a witness. <i>See Great Am. Ins. Co. of N.Y. v. Vegas Const. Co.</i>, 251 F.R.D. 534, 539 (D. Nev. 2008) ("The fact that an organization no longer has a person with knowledge on the designated topics does not relieve the organization of the duty to prepare a Rule 30(b)(6) designee."). To date, it has refused to do either.</p> |
| 3. Topic 8 – Bard's communications to patients and/or the general public regarding the replacement of filters in the market and/or the introduction of new filters into the market, including Bard's consideration of whether to send such communications, whether or not sent. | |

| Plaintiffs' Position | Defendants' Position |
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| | | |
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| | <p>This topic seeks testimony concerning Bard's communications to patients and the general public concerning the transition from one generation of filters to the next. Bard has refused to provide a witness in response to this topic, and instead has simply pointed to written discovery responses. The law is clear that Bard may not simply "elect to supply the answers in a written response to an interrogatory" in response to a Rule 30(b)(6) deposition notice or subpoena request." <i>Great Am. Ins. Co.</i>, 251 F.R.D. at 539 (internal quotation and citation omitted).</p> | <p>Defendants have explained to Plaintiffs that they do not engage in direct-to-patient advertising, and Plaintiffs have served certain Requests for Admissions to that effect. Specifically, Plaintiffs recently served Requests for Admissions asking Defendants to admit that they do not engage in direct-to-consumer advertising and that Bard did not engage in direct-to-consumer marketing efforts, aside from the patient brochures previously produced which Defendants identified to Plaintiffs' counsel during the meet and confer process. Defendants have also explained to Plaintiffs that they do not have any ability to identify filter recipients/patients, and Plaintiffs' Requests for Admission seek this discovery as well. During the meet and confer process, Defendants identified to Plaintiffs prior discovery responses providing some of the information Plaintiffs seek. Plaintiffs have not informed Defendants why the discovery previously identified is insufficient or what information above and beyond that discussed above is sought. Plaintiffs have simply demanded a witness on this topic. Defendants do not believe that the discovery sought is within the scope of permissible discovery governed by Rule 26.</p> |
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| | <p>4. Topics 9 and 10.</p> <p>9. Communications to Bard from physicians, healthcare professionals, or healthcare providers, either written or oral, concerning the safety and efficacy of Bard IVC Filters.</p> <p>10. Communications to Bard from patients, either written or oral, concerning the safety and efficacy of Bard IVC Filters.</p> |
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| Plaintiffs' Position | Defendants' Position |
|---|---|
| <p>These topics concern communications to Bard from physicians and others concerning the safety and efficacy of Bard IVC Filters. Bard has again simply identified documents it has produced, asserted that it cannot provide a witness to testify to these communications, and questioned whether this information is relevant to class certification.</p> <p>Communications from doctors and patients concerning Bard's filters, and how Bard responded, are important to counter Bard's arguments that the propriety of a medical monitoring program raises individual questions. If Bard handled these questions in a way that showed that Bard itself treated class members in a common way,</p> | <p>Defendants have repeatedly explained to Plaintiffs that there are no records of oral conversations between Bard employees and physicians, outside the ESI previously produced. Defendants have also explained that, generally speaking, Bard employees do not communicate directly with patients, unless the patients contact Bard with a question or complaint. Any general question received from a patient or physician would be referred to the Medical Services & Support personnel. Any complaint/report of complication would be referred to field assurance and would result in the opening of a complaint file. Documentation regarding MS&S calls received and complaint files have been</p> |

such evidence is potentially important for class certification.

Plaintiffs do not seek to depose a witness on the substance of Bard's complaint files and MS&S communication log. Rather, Plaintiffs seek to testimony concerning Bard's procedures for maintaining these records and processing the referenced communications.

previously produced and are within Plaintiffs control.

For the first time, in their section of this joint submission, Plaintiffs state:

"Plaintiffs do not seek to depose a witness on the substance of Bard's complaint files and MS&S communication log. Rather, Plaintiffs seek to [sic] testimony concerning Bard's procedures for maintaining these records and processing the referenced communications." This new information is critical to Defendants' articulation of their position on this topic, as the subject matter of complaint handling and related policies and processes was the subject matter of a prior 30(b)(6) deposition taken by 2 members of the Plaintiffs' Steering Committee and attended by 4 members of that committee, including Mr. Lopez, who is co-lead counsel in this case.

Contrary to their current stated position, during the meet and confer process, Defendants confirmed that Plaintiffs' Topic 9 and 10 do not seek policies and procedures regarding either MS&S or the complaint handling process; rather, they sought a witness or witnesses to speak to the substance of the thousands of pages of complaint files and MS&S phone and communication logs. Defendants explained that they do not believe it is possible to produce a witness or witnesses to give the testimony Plaintiffs seek, nor do Defendants believe the discovery sought is within the scope of what is permissible according to Rule 26, particularly given this discovery is purported class certification discovery. Plaintiffs have declined to explain why the discovery sought is necessary for class certification.

5. Topic 13 –Bard's efforts to determine the logistics, strategy, and costs of a monitoring program for patients implanted with Bard IVC filters.

Plaintiffs' Position

In refusing to provide a witness for this topic, Bard has pointed to a deposition taken on REACH, a time-limited program that Bard's corporate designee testified was not a medical monitoring program. The question of whether Bard ever considered implementing a medical monitoring program is plainly relevant to

Defendants' Position

During the course of the meet and confer process, Defendants identified for Plaintiffs the 30(b)(6) deposition regarding Bard's REACH program, which is a program whereby physicians are able to register their patients who have been implanted with an IVC filter for contacts reminding them to follow-up with their

1 Plaintiffs' core demand for such a program
 2 in this case, and to class certification. For
 3 example, if Bard argues that even
 4 identifying class members is infeasible or
 impracticable, Plaintiffs are entitled to
 discover the basis of that assertion,
 including whether Bard ever came to that
 conclusion prior to the commencement of
 litigation.

5 physicians. The aforementioned
 6 deposition was taken in the MDL in late
 7 August 2016, well after this case was
 transferred to this MDL. During that
 8 deposition, Kim Romney, the designated
 9 deponent explained that the REACH
 10 program was the first and only such
 11 program offered by Bard with respect to
 12 its IVC filters.

13 Plaintiffs have explained that what they
 14 seek is a witness to testify regarding what
 other efforts Bard may have undertaken to
 15 track filters/outcomes/and the necessity for
 individual filter patient follow-up.
 16 Defendants have explained that (a) they do
 17 not know the identities of Bard filter
 recipients, and (2) it is Bard's view that the
 18 follow-up appropriate for any given filter
 recipient is a decision to be made by each
 19 patient's physician. Defendants requested
 20 that Plaintiffs serve written discovery in
 lieu of pursuing a witness to testify
 21 regarding this topic. While Plaintiffs
 22 initially agreed to consider doing so, they
 23 subsequently declined.

24 Defendants believe that the most efficient
 25 means for obtaining the discovery
 26 Plaintiffs seek is through written
 discovery, and in fact certain aspects of
 27 this topic are covered in the Requests for
 Admissions that Defendants suggested
 Plaintiffs serve in lieu of pursuing this
 topic – i.e., Plaintiffs seek admissions
 from Bard that "Bard does not have
 information about the location of patients
 that have received implants, retrievals,
 and/or monitoring of Bard IVC Filters[.]"
 Plaintiffs have declined to provide any
 rationale for why this discovery is
 necessary, above and beyond those
 Requests for Admissions previously
 served, at this class certification stage. If
 Plaintiffs want to know whether Bard
 "came to the conclusion that it is not
 possible for Bard to identify class
 members prior to the commencement of
 litigation," that information is easily
 knowable, as it has been Bard's consistent
 position over more than a decade of
 litigation, and Plaintiffs can easily seek
 reconfirmation of this through written
 discovery.

28 **6. Topic 14 – Communications from Bard to physicians, healthcare professionals,
 and/or patients about the risks associated with non-retrieval of Bard IVC Filters.**

| | <u>Plaintiffs' Position</u> | <u>Defendants' Position</u> |
|---|---|---|
| 1 | This topic concerns communications from Bard to physicians, healthcare professionals, and/or patients concerning the risks associated with non-retrieval of Bard IVC Filters. Plaintiffs limited this topic to Bard's efforts to update physicians and others about new literature as it became available to Bard concerning risks of non-retrieval. To date, Bard has pointed to documents it has produced, but has refused to provide a witness. Bard has not explained why preparation of a corporate witness on this topic would require interviews "hundreds" of individuals with knowledge about this topic. Indeed, like Topics 5 and 7, testimony on this topic would be limited to core communications; decisions as to what those communications would say and who they would go to would not likely involve the hundreds of people that Bard claims it does. | During the course of meeting and conferring, Plaintiffs explained that this topic is intended to depose a witness regarding "communications updating physicians as to new literature as it became available that pertained to the risk of non-retrieval." Defendants have provided an index to Plaintiffs identifying the specific Bates numbers for responsive documents produced. To the extent Plaintiffs wish to know which medical literature regarding IVC filters was approved by Bard for dissemination to physicians, Defendants also provided the Bates numbers for all such documents, including the corporate approval files for each, which will include the corporate approval forms of each and comments of Bard employees regarding same. |
| 7. Topic 15 –Bard's efforts to identify the safety status of Bard IVC Filters for indwell times in excess of two months. | | |
| 24 | <u>Plaintiffs' Position</u> | <u>Defendants' Position</u> |
| 25 | Plaintiffs have clarified that this topic is limited to Bard's efforts to identify the safety of Bard's filters for patients who are implanted with the filter for more than two months, as compared with removal, and whether those whose filters are not removed would benefit from monitoring of the placement and condition of their | Defendants have explained that, in Defendants' view, Plaintiffs seek a medical opinion regarding the risk/benefit analysis of retrieval versus permanent use, and that it is Defendants' view that to provide such information would be the practice of medicine, in which Bard does not engage. Defendants have further explained to |

filters. Bard's response to this topic is to characterize it as seeking a medical opinion concerning risk/benefit analyses of retrieval versus permanent use, and to request that Plaintiffs serve written discovery on this topic. Plaintiffs are not seeking a medical opinion from Bard on this topic, but instead, only to determine what efforts Bard undertook, if any, to understand the risks that patients would face in not removing their filters, and whether Bard considered the possible benefits that monitoring would bring such patients. This is the relief that Plaintiffs seek in this case, and it will be Plaintiffs' ultimate burden to show that such monitoring would mitigate the risks that Bard's filters pose, and burden on class certification to show that this question is susceptible to common proof. Plaintiffs are entitled to testimony about Bard's views during the relevant time period on this central question.

Plaintiffs that all of their retrievable IVC filters are cleared by FDA for permanent use, and there is no time limitation on attempted retrieval, rather, that is in the discretion of each filter recipient's physicians.

Defendants have informed Plaintiffs that they do not know (for HIPAA reasons) the identity of patients who receive filters and have no way to track them. When a filter should be removed is a case-by-case decision made by a patient's medical care provider(s). As such, Bard has informed the plaintiff that it does not track and has no way of tracking the condition of its filters in particular patients. For these reasons, Defendants do not have information responsive to this request, and has informed Plaintiffs of that.

To the extent Plaintiffs intend this topic to be limited to testing related to complications, as Plaintiffs know, it is Defendants position that the risks associated with all IVC filters exist at all times that a filter remains within a patient's body. The subject matter regarding risks associated with filters and as those risks pertain to specific time periods, those issues have been the subject of multiple prior depositions in this litigation, including expert witness depositions.

Defendants asked Plaintiffs to serve written discovery (Requests for Admissions) so that Defendants could provide Plaintiffs with the binding statements they seek. Plaintiffs have declined and simply demand a witness on this topic. Defendants do not believe a 30(b)(6) witness on this topic is the most efficient way of providing the information Plaintiffs seek (or more accurately, confirming that the information does not exist). Moreover, Plaintiffs have declined to explain why the discovery sought is necessary for class certification.

1 DATED this 5th day of December 2016.

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14 **CERTIFICATE OF SERVICE**

15 I hereby certify that on December 5, 2016, the foregoing was electronically filed
16 with the Clerk of Court using the CM/ECF system which will automatically send email
17 notification of such filing to all attorneys of record.

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19 s/ Deborah Yanazzo

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